Evaluating the Efficacy of Pediatric Lipid Screening Alerts
(NCT04118348)

Study Protocol with Statistical Analysis Plan

October 12, 2021

Study Protocol

Purpose

The purpose of the study was to evaluate, prospectively, the impact of different healthcare system alerts on the prescription of lipid panel screenings for pediatric Geisinger patients (9-11 years old), following current US pediatric guidelines. This study aimed to quantify the relative effectiveness of different alerts and combinations of alerts on provider prescribing behavior and patient uptake of screening.

Introduction

Cardiovascular disease is the leading cause of death in the United States, with more than 600,000 people dying annually. In 2008, the American Academy of Pediatrics introduced recommendations for lipid screening for all at-risk youth between 2-11 years of age. More aggressive guidelines have been recommended in 2011 and 2016; however, global screening for lipid disease in the pediatric population has not increased sufficiently.

Increasing salience of the guidelines with alerts may help change providers' thought process and workflow, as electronic alerts to physicians have generally been found to be effective in improving clinician behavior during visits and increasing adherence to clinical recommendations in primary care. To our knowledge, researchers have not yet systematically examined the effect of electronic health record (EHR) alerts on pediatric lipid screening.

A randomized controlled study examining provider and patient response to alerts in electronic health records was conducted to determine the most effective approach to improve provider and patient compliance with evidence-based medicine practices. Pediatric patients between the ages of 9-11 who were not previously screened for lipids were randomized to a delayed-intervention control condition or one of three different alert types (passive health maintenance topic, pop-up best practice alert, or a combination of both) that their attending providers received.

Methods

Sample

For the primary analysis, researchers enrolled 13,480 eligible pediatric participants according to the inclusion and exclusion criteria described below. Eligible participants were patients aged 9 to 11 years of age who were seen within a Geisinger primary care, cardiology, urgent care, or nutrition clinic, or who had an endocrinology visit within 6 months of study launch (October 11, 2019). Researchers did not include patients with a completed lipid screen in Geisinger's EHR and those who had familial hypercholesterolemia based on prior screening (ICD-10 code E78.01 or Z83.42). For all participants in this study, researchers only examined orders made during the first visit during the study period. That is, data for orders made during a subsequent visit were not gathered (even when looking 6 months after a visit).

Experimental conditions

Patients who were eligible for this study were randomly assigned into one of four groups through a random number generator added to Geisinger's EHR, which was run automatically at the time of the visit. Researchers compared different combinations of a passive alert in the health maintenance topic (HMT) panel and a best practice alert that appears in the best practice panel, while also popping up when order panels are opened (BPA): (1) the control group did not receive an alert during the study period; (2) the BPA and HMT group received a BPA and HMT; (3) the BPA-only group received a BPA; and the (4) HMT-only group received an HMT.

The BPAs and HMTs prompted providers to discuss and order a non-fasting lipid screening test at the time of the visit with the patient. In addition, for patients who were randomized to receive the HMT (with or without BPA), their families received a prompt in their patient portal chart stating that a health maintenance topic had been sent. Aside from receiving the alerts, providers and patients were not aware that there were different conditions or that a patient was randomly assigned to one.

Outcome measures

The binary primary outcomes were lipid screening orders by providers and screening completions by eligible patients within one week of the orders. After initial examination of the data, the researchers also conducted exploratory analyses of completions six months after the orders in a post-hoc analysis to account for possible delays in scheduling tests or getting results. They also compared the results to a similar cohort of eligible patients with similar kinds of visits in the 6 months before the intervention (as a pre-post test).

Statistical Analysis Plan

As of the writing of this plan, primary and additional analyses have already been completed.

Primary Analyses

Binary logistic generalized linear mixed models (GLMMs) were used to analyze the primary outcomes – lipid screening orders and completions one week after the visit – as a function of condition, with the provider added to the model as a random effect. As the researchers were interested in the comparison between the experimental groups and the control group, as well as the relative effectiveness between the experimental groups, they conducted contrasts between all 4 groups with a Tukey correction for multiple comparisons. Odds ratios (ORs) were calculated, along with asymptotic 95% confidence intervals (CIs); two-tailed p-values < 0.05 were used to determine statistical significance. To represent effect size, the standardized statistic, Cohen's d, was estimated using the formula $LogOddsRatio \times \sqrt{3}/\pi$ (Hasselblad & Hedges, 1995). Raw percentages and 95% CIs were also presented.

Additional Analyses

Epic Storyboard (a newly introduced method of showing information to the provider in the EHR) was introduced on November 1, 2019. As Epic Storyboard might have changed the way

providers engaged with alerts, the researchers reran the models including an interaction term between the presence of Epic Storyboard (i.e., patient encounters after November 1, 2019) and the conditions.

The same kind of GLMM model as used in the primary analyses was also used to examine the effect of the experimental conditions on completions 6 months after the intervention.

To conduct pre-post comparisons, the researchers examined the records of 12,627 eligible patients with the same kind of visits 6 months prior to the study period. The four experimental conditions were compared against this pre-alert group using the same kind of GLMM model used in the primary analyses. Instead of a Tukey correction, a Dunnett correction was applied since all of the contrasts were made against one group, the pre-alert group.